

*Application No. 09/885568*  
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*Amendment*  
*Attorney Docket No. S63.2B-9515-US01*

**Remarks**

***Rejections***

***Double Patenting***

Claims 1-6, 9 and 10 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 14 and 24-36 of copending Application No. 09/696378.

Applicants do not agree but in order to expedite prosecution have included herewith, a terminal disclaimer, obviating this rejection.

***35 U.S.C. §102(b)***

Claim 14 has been rejected under 35 U.S.C. §102(b) as being anticipated by Bland et al. (U.S. 5,427,842). The Office Action asserts that Bland et al. has a balloon for a medical device (angioplasty) which must inflate to a controlled size and should not stretch to a larger size, but cannot readily tear which is formed from tear resistant multilayer film comprising alternating layer of relatively stiff and ductile polymeric materials (col. 1, lines 10-50). The Office Action further asserts that the tear resistant film comprising more than 5 layers overlaps the claimed range of at least 7 up to 50 laminate layers (col. 3, lines 30-50).

Applicants traverse the rejection.

Claim 14 of the present invention is directed to medical balloons having 7 to 25 laminate layers of polymer.

***Bland et al., US 5427842***

Bland et al. describe a tear resistant film comprising more than five layers situated one on the other in a parallel array. The layers are individually selected from a stiff polyester or copolyester, a ductile polymeric material, and optionally, an intermediate material. The stiff polyester or copolyester is oriented in at least one direction. (Abstract).

Specifically, Bland et al. describe and claim the use of these films in *security control laminates*, and while angioplasty balloon are mentioned generally in the Background of the Invention, there is no specific teaching as to making angioplasty balloons, and how many layers would be employed in making angioplasty balloons. Furthermore, more than 5, could

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refer to 6 layers, and does not necessarily have to refer to about 7 to about 25 layers.

Consequently, we submit Bland et al. does not anticipate claim 14 because there is no specific teaching as to medical balloons, and there is no specific teaching as to how many layers would be employed in the formation of a medical balloon and there is no indication how the adhesive backed glazing film would be used in a medical device.

Thus, with respect to claim 14 of the present invention specifically, Bland et al. do not specifically teach medical balloons with 7 to 25 layers and consequently, Bland et al. does describe each and every limitation of claim 14 as required under 35 U.S.C. §102(b). Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. §102(b) as being anticipated by Bland et al., US 5427842.

***35 U.S.C. §103(a)***

Claims 1-6 and 9-13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Boretos (US 4,254,774) in view of Zdrahala (US 5,156,785). The Office Action asserts that Boretos teaches a balloon catheter which has a one-piece unitary construction which minimizes the possibility of detachment or separation of portions thereof accidentally in a critical area of the body where harm may be incurred to the patient, such as in the area of the brain or lungs (col. 2, lines 60-70). To form the balloon, the catheter tubing is heated locally in the area where the balloon is desired and then inflated (col. 5, lines 40-70). The Office Action asserts that Boretos teaches that the catheter tubing may comprise any suitable thermoplastic material such as polyurethanes and copolyester polymers (col. 4, lines 35-45).

Applicants traverse the rejection.

Claim 1 of the present application is directed to a balloon for a medical device comprising a polymer matrix material and a plurality of fibers distributed in the matrix material and operatively adhering thereto to provide reinforcement thereof, the fibers being distributed in a longitudinal or helical direction relative to the balloon axis and composed of a material which has a greater tensile strength than the matrix material.

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*Boretos, US 4,254,774*

Boretos is directed to a single-lumen, one piece catheter approximately 0.04 inch in diameter with an integral balloon at its end having a wall thickness of 0.005 inch or less, sufficiently small to be retractile by suction into the catheter and to be extensible at a desired site by fluid pressure (Abstract). See also claim 1. The balloon may comprise any suitable thermoplastic or thermosensitive material that can be made in the form of tubing, for example, polyurethanes, copolyester polymers, thermoplastic rubbers, silicone-polycarbonate copolymers, polyethylene ethyl-vinyl-acetate, or combinations of these and/or others.

It is admitted on page 4 of the Office Action that Boretos fails to teach the plurality of fibers being distributed in a selected direction relative to the balloon axis and composed of a material which has greater tensile strength than the matrix material as described in the present application.

Applicants submit that, in fact, Boretos fails to teach any reinforcement of either the catheter tubing or the balloon.

*Zdrabala, US 5,156,785*

Zdrabala describes extruded catheters and other flexible plastic tubing which may be manufactured with improved rotational and/or longitudinal stiffness, compared with catheters made of more conventional plastics. A tubing of liquid crystal polymer plastic-containing material may be extruded through a tube extrusion die while rotating the inner and outer die walls to provide circumferential shear to the extruded tube. Thus the liquid crystal polymer is oriented in a helical manner to provide improved properties, including greater rotational stiffness. (Abstract)

Zdrabala fails to teach a balloon with liquid crystal polymer.

We submit that the combination of Boretos with Zdrabala, is lacking at least one important element of the claimed invention, i.e. the polymer *balloon* as taught and claimed in the present application. The combination neither teaches nor suggests the balloons of the present application. Nor does Zdrabala suggest any post-extrusion processing of the reinforced tubing described therein as would be required for formation of a balloon according to the present invention.

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Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-6 and 9-13 under 35 U.S.C. §103(a) as being unpatentable over Boretos (US 4,254,774) in view of Zdrahala (US 5,156,785).

Claims 7-8 and 15-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Boretos in view of Zdrahala as applied to claims 1-6 and 9-13 above, and further in view of Bland et al. (US 5,427,842). The Office Action asserts that Boretos teaches the balloon catheter tubing for a medical device but fails to teach laminate layers comprising alternating series of fiber-containing fiber-free layers. Zdrahala teaches the catheter tubing for medical devices wherein the catheter tubing contains from 1 to 35 weight percent of the liquid crystal polymer (col. 5, lines 16-30), but fails to teach the ratio of the total thickness of the two types of layers in the absence of a showing of unexpected results, it is the examiner's position that the claimed range of from about 5 to about 15, for the ratio of liquid crystal polymer fiber blend layer to polymer layer, is the result of routine experimentation. Zdrahala fails to teach the alternating series of fiber-containing and fiber-free layers.

Applicants traverse the rejection.

Claim 7 is directed to a balloon having laminate layers which include alternating series of fiber-containing and fiber-free layers. Claim 8 depends from claim 7.

Claim 15 which depends from claim 14 discussed above, is directed to a balloon composed of an alternating series of A layers composed of a single polymer and B layers composed of a blend of matrix material and LCP polymer. Claims 16-20 depend from claim 15.

Claim 21, which also depends from claim 14 discussed above, is directed to a balloon wherein at least some of the laminate layers are formed from an extruded blend of a matrix polymer material and an LCP polymer material, and the LCP polymer forming fibers within the matrix polymer with the fibers oriented substantially in a longitudinal or helical direction relative to the balloon axis.

Claim 22, which also depends from claim 14 discussed above, is directed to a balloon including alternating laminate layers of (A) selected from the group consisting of compliant and semi-compliant polymers and (B) a material formed from a blend of an LCP polymer with a material selected from the group consisting of compliant and semi-compliant polymers. Claim 23 depends from claim 22.

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Boretos, Zdrahala and Bland et al. have been discussed above. Boretos describes a single-lumen, one piece catheter, but fails to describe LCP fibers or any type of reinforcement of either the tubing or the balloon.

Zdrahala describes extruded catheter tubing and other flexible plastic tubing with improved rotational and/or longitudinal stiffness, compared with catheters made of more conventional plastics, having tubing of liquid crystal polymer (LCP) plastic-containing material, but fails to teach balloons formed with LCP plastic-containing material.

Bland et al. describes laminates having more than 5 layers, but fails to teach that any of the layers have LCP, or any type of fiber or other reinforcement material in a matrix polymer.

This combination, as with the combination of Boretos and Zdrahala, still lacks the most important element of the claimed invention, i.e. the polymer balloon as taught and claimed by the present invention. There is no suggestion or motivation to further process the extruded tubing of Zdrahala with the LCP blended in a matrix polymer, into a balloon, whether the blend is included as a layer or not.

Consequently, the combination of Boretos, Zdrahala and Bland et al., does not lead one of skill in the art to a balloon having laminate layers of a blend of a matrix polymer with LCP, as required by claims 7, 15, 21 and 22. Claim 8 depends from claim 7 and is patentable for at least the reasons that claim 7 is patentable. Claims 16-20 depend from claim 15 and are patentable for at least the reasons that claim 15 is patentable. Claim 23 depends from claim 22 and is patentable for at least the reasons that claim 22 is patentable.

Applicants respectfully request withdrawal of the rejection of claims 7-8 and 15-23 under 35 U.S.C. §103(a) as being unpatentable over Boretos in view of Zdrahala as applied to claims 1-6 and 9-13 above, and further in view of Bland et al. (US 5,427,842).

#### CONCLUSION

Claims 1-23 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

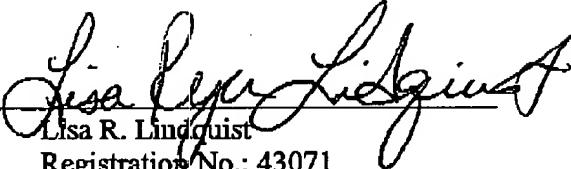
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Respectfully submitted,

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